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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,569	01/16/2001	Roger J. Davis	10363-003004 / UMMC Ref.:	9227
7590	03/19/2002			
J. PETER FASSE Fish & Richardson P.C. 225 Franklin Street Boston, MA 02110-2804			EXAMINER TAYLOR, JANELL E	
			ART UNIT	PAPER NUMBER

1634  
DATE MAILED: 03/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/761,569	DAVIS ET AL.
	Examiner	Art Unit
	Janell Cleveland Taylor	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1,32-44 and 50-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1,32-44 and 50-52 are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \*    c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)                            4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                    6) Other: *Detailed Action*.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1, drawn to a mitogen-activated protein kinase kinase, classified in class 530, subclass 350.
  - II. Claims 32-38, drawn to antibodies that bind the polypeptide of claim 1, classified in class 424, subclass 130.1.
  - III. Claims 39-41 and 44, drawn to a method of measuring the activity of a mitogen-activated protein kinase kinase (MKK), classified in class 435, subclass 7.1.
  - IV. Claim 42, drawn to a method for measuring the synthesis of MKK in a biological test sample, classified in class 435, subclass 7.2.
  - V. Claims 43, 50, drawn to a method for measuring the level of expression of MKK in a test sample, classified in class 435, subclass 7.1.
  - VI. Claims 51-52, drawn to a method of treating an MKK disorder, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to proteins and antibodies.

Antibodies have different functions than proteins, i.e., the antibody attaches to the

protein, often disabling it from functioning, and the protein is useful for carrying out various cellular functions. The protein is capable of functioning in the cell without the antibody being present, and can be used by the practitioner to create enzymes, or for diagnostic testing. Furthermore, the peptide is capable of functioning without the antibody being present in the cell, in fact, the protein usually cannot function when the antibody is present.

3. Inventions I-II and V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to products and methods. The methods are drawn to measuring the activity of MKK, methods of measuring the synthesis of MKK, methods of measuring the level of expression of MKK, and methods of treating an MKK disorder. The products themselves are not even required in the claims of group V and group VI.

4. Inventions I-II and III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of claims from group III and IV are drawn to measuring the activity of MKK or the synthesis of MKK. The product may be used in different processes. For example, the product is useful as a kinase.

5. Inventions III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods. Each method has a different function, as it has a different purpose. For instance, the methods of group III measure the activity of MKK, while the methods of group IV measure the synthesis of MKK. These are different function. Furthermore, they require different steps and therefore have different modes of operation. These claims are different from group V as well, which measures something entirely different: the level of expression of MKK. They (claims of group V) measure a different product (RNA) and therefore have a different function. Furthermore, they have a different mode of operation. The claims of group VI are further different from those of groups III-V. They are drawn to treating an MKK disorder by administering a reagent that modulates MKK activity. This has a different effect than the other groups, a different mode of operation, and a different function, as it requires the use of product not found in the other groups.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Conclusion**

Any inquiries of a general nature relating to this application, including information on IDS forms, status requests, sequence listings, etc. should be directed to the Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 872-9306 or 872-9307 (after final). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

March 14, 2002

  
Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600